Automated Dissociated Enhanced Lanthanide Fluoro Immunoassay System (AutoDELFIA) for the Determination of Thyrotropin (TSH), 17-Hydroxyprogesterone (17-OHP), and Immunoreactive Trypsin (IRT)

Tracking No. CN 006

Version 2.1

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I. Title: Automated Dissociated Enhanced Lanthanide Fluoro Immunoassay System (AutoDELFIA) for the Determination of Thyrotropin (TSH), 17-Hydroxyprogesterone (17-OHP), and Immunoreactive Trypsin (IRT).

II. Principle

The AutoDELFIA for the determination of TSH, 17-OHP, and IRT is a solid-phase, time-resolved, fluoroimmunoassay developed by Perkin-Elmer. The label for the assay is a lanthanide metal, europium (Eu), which has a much slower fluorescence decay time than non-specific background fluorescence. The Eu label is excited by an energy beam, and the decaying energy is measured. Measurement is at a time when the background fluorescence has already decayed, eliminating interfering substances. The duration of each measurement is one millisecond, and consists of about 1000 excitation cycles. These factors result in time-resolved fluorometric assays having increased sensitivity.

The TSH immunoassay uses the "sandwich principle" in which two mice monoclonal antibodies are directed against two separate antigenic determinants on the TSH molecule. The tracer diluted with buffer is used to elute the TSH antigen from a 1/8" disc punched from the blood spot specimen. During an incubation period, the TSH simultaneously binds with the antibody coated on the walls of the wells and the Eu-labeled antibody. At the completion of the immunoreaction, the wells are washed and aspirated to remove the unbound Eu-labeled antibody. The low pH of the Enhancement Solution effectively dissociates the Eu ions from the labeled compound. The free Eu ions, with components of the Enhancement Solution, then form fluorescent chelates. The pulses counted from the decaying fluorescence are proportional to the concentration of TSH in the specimens.

The 17-OHP immunoassay is a "competitive" immunoassay based on the competitive reaction between Eu-labeled 17-OHP and 17-OHP from the specimen for binding sites on the 17-OHP specific polyclonal antibody which in turn is specific for the antibody coated on the walls of the reaction well. The polyclonal antibody is diluted and dispensed into the wells to allow it to react with the coated antibody. The diluted tracer is then added to the well to allow the competitive reaction to occur. At the completion of the immunoreaction, the wells are washed and aspirated to remove the unbound Eu-labeled 17-OHP. The Enhancement Solution dissociates the Eu ions from the labeled compound. The free Eu ions form a fluorescent chelate. The pulses counted from the decaying fluorescence are inversely proportional to the concentration of 17-OHP in the specimens.

The IRT immunoassay uses the "sandwich principle" in which two mice monoclonal antibodies are directed against two separate antigenic determinants on the IRT molecule. The tracer diluted with buffer is used to elute the IRT antigen from a 1/8" disc punched from the blood spot specimen. During an incubation period, the IRT simultaneously binds with the antibody coated on the walls of

the wells and the Eu-labelled antibody. At the completion of the immunoreaction, the wells are washed and aspirated to remove the unbound Eu-labelled antibody. The low pH of the Enhancement Solution effectively dissociates the Eu ions from the labeled compound. The free Eu ions, with components of the Enhancement Solution, then form fluorescent chelates. The pulses counted from the decaying fluorescence are proportional to the concentration of IRT in the specimens.

A copy of this protocol is in the Supervisor's PC. To access, login, click **Management/Maintenance/SOP** and select the TSH/17-OHP assay.

III. Specimen Collection and Type

Newborn blood spots from a heel puncture are collected on special filter paper. The filter paper and test request form with identification and demographic information are sent to NAPS laboratories for testing. Refer to Newborn Screening Accession and Reporting at the NAPS Lab protocol.

IV. Equipment and Supplies

- A. Equipment
 - 1. Supplied by Wallac
 - a. Hardware per laboratory
 - 1) AutoDELFIA
 - 2) Barcode printer
 - 3) Puncher
 - 4) Barcode reader
 - b. PC's and other data management equipment
 - 1) PC to run AutoDELFIA
 - 2) Specimen Gate workstation PC's
 - 3) Supervisor's PC
 - 4) Server
 - 5) Laser printer
 - 6) Router and hub

B. Supplies

- 1. Supplied by Wallac
 - a. Deep well/microtiter tray holder
 - b. SQC Rack 73
 - c. Cap holder
 - d. Dilution vessels
 - e. Wallac pipette tips

- f. Computer paper
- g. Printer toner/ink cartridge
- h. Barcode labels
- i. Barcode ribbons
- j. DAT tapes

2. Supplied by NAPS Laboraory

- a. Pipettor, fixed volume, 1500 µL
- b. Pipettor, adjustable, 0-1000 μL and tips
- c. Tubes, plastic, with 3 different color-coded caps, 12x75 mm
- d. Tubes, glass or plastic, 16x125 mm
- e. Beakers, 250 mL
- f. Cotton swabs
- g. Transfer pipets, disposable

V. Reagents

A. Supplied by Wallac

1. AutoDELFIA Neonatal hTSH Kit

All reagents are stored refrigerated, 2-8°C. Use until date of expiration. Each box of TSH reagents contains 12 plates and reagents for 12 plates. Included are 3 barcode labels for the reagent cassette encoded for analyte and lot number. Each box contains:

a. hTSH Standards*

Name	Concentration**					
A	1	mIU/L				
В	10	mIU/L				
C	25	mIU/L				
D	50	mIU/L				
E	100	mIU/L				
F	250	mIU/L				

^{* 6} Standard Cards, 6 blood spots per card

b. hTSH System Quality Controls (SQC)*

Name	Concentration**

^{**} Approximate values. Actual concentrations may change slightly from lot to lot

CL	10	mIU/L
CH	50	mIU/L

^{* 6} Control Cards, 6 blood spots per card

- c. Anti-hTSH microtiter strips, 12 wells per strip, 8 strips per tray, 12 trays.
- d. Anti-hTSH Eu tracer in Tris-HCl buffered (pH 7.8), salt solution with bovine serum albumin, mouse IgG, and <0.1% sodium azide as preservative, approximately 20 μg/mL, 1.1 mL/vial, 6 vials.
- e. Neo hTSH Assay Buffer, Tris-HCl buffered (pH 7.8), salt solution with bovine serum albumin, bovine globulin, Tween 40, polyethylene glycol 6000, red dye, <0.1% sodium azide as preservative, 120 mL/bottle, 3 bottles.

2. AutoDELFIA Neonatal 17α-OH-ProgesteroneL Kit

All reagents are stored refrigerated, 2-8°C. Use until date of expiration. Each box of 17-OHP reagents contains 12 plates and reagents for 12 plates. Included are 3 barcode labels for the reagent cassette encoded for analyte and lot number. Each box contains:

a. 17-OHP Standards*

Concentration**						
0	nmol/L					
5	nmol/L					
15	nmol/L					
30	nmol/L					
100	nmol/L					
300	nmol/L					
	0 5 15 30 100					

^{* 6} Standard Cards, 6 blood spots per card

b. 17-OHP System Quality Controls (SQC)*

Name	Conc	entration**
CL	20	nmol/L

^{**} Approximate values. Actual concentrations may change slightly from lot to lot

^{**} Approximate values. Actual concentrations may change slightly from lot to lot.

	Appe	endix 5G
CM	50	nmol/L
CH	100	nmol/I

^{* 6} Control Cards, 6 blood spots per card

- c. Anti-Rabbit IgG microtiter strips, 12 wells per strip, 8 strips per tray, 12 trays.
- d. 17-OHP antiserum, rabbit polyclonal, 2.8 mL, 4 vials.
- e. 17-OHP Eu tracer, lypophilized, in Tris-HCl buffered (pH 7.8), salt solution with bovine serum albumin and Dextran T10, <0.1% sodium azide as preservative, 4 vials.
- f. 17-OHP Assay Buffer, Tris-HCl buffered (pH 7.8), salt solution with bovine serum albumin, Tween 40, polyethylene glycol 6000, calcium chloride, danazol, inert red dye, <0.1% sodium azide as preservative, 120 mL/bottle, 3 bottles.

3. AutoDELFIATM Neonatal IRT Kit

All reagents are stored refrigerated, 2 - 8° C. Use until date of expiration. Each box of IRT reagents contains 12 plates plus reagents for 12 plates plus 3 barcode labels for the reagent cassette encoded for analyte and lot number. Each box contains:

a. IRT Standards

Name	Concentration*	Quantity**
A	0 ng/mL	
В	25 ng/mL	
C	50 ng/mL	
D	100 ng/mL	
E	200 ng/mL	
F	400 ng/mL	

- * Approximate values. Actual concentrations may change slightly from lot to lot.
- ** 6 Standard Cards, 6 blood spots per card
- b. IRT System Quality Controls (SQC)

Level Concentration* Quantity**

^{**} Approximate values. Actual concentrations may change slightly from lot to lot.

Appendix 5G
I (Low) 20 ng/mL
II (Medium) 50 ng/mL
III (High) 100 ng/mL

- * Approximate values.
- ** 6 Control Cards, 6 blood spots per card
- c. Anti-IRT microtiter strips, 12 wells per strip, 8 strips per tray, 12 trays.
- d. Anti-IRT Eu tracer in Tris-HCl buffered (pH 7.8) salt solution with bovine serum albumin, mouse IgG, and <0.1% sodium azide as preservative, approximately 20 μg/mL, 1.1 mL/vial, 6 vials.
- e. Neo IRT Assay Buffer, Tris HCl buffered (pH 7.8), salt solution with bovine serum albumin, bovine globulin, Tween 40, polyethyleneglycol 6000, red dye, <0.1% sodium azide as preservative, 120 mL/bottle, 3 bottles.
- 4. Enhancement Solution, with Triton X100 (registered trademark of the Rohm and Haas Co.), acetic acid, and chelators. Store protected from light at 2-8°C. Use until expiration date. 250 mL/bottle, 8 bottles/box.
- 5. Wash Concentrate, concentrated Tris-HCl buffered salt solution, pH 7.8, with Tween 20 and Germall II (registered trademark of Sutton Laboratories Inc.) as preservative. Store at 2-25°C. Use until expiration date. 250 mL/bottle, 8 bottles/box.
- B. Supplied by GDL

Blood Spot Tray Quality Control (TQC), enriched with TSH and 17-OHP. Store frozen. Use until date of expiration.

- C. Supplied by NAPS Laboratories
 - 1. Distilled water or NCCLS Type 1 water
 - 2. Household bleach (Sodium Hypochlorite, 5.25%)
 - 3. Isopropyl alcohol or ethanol (Do not use denatured ethanol).

VI. Calibration and Quality Control

A. Calibration

1. Refer to Sections V.A.1.a, V.A.2.a, and V.a.3.a. Calibrators are supplied ready for use in the TSH, 17OHP, and IRT kits.

2. Blood spot calibrators are punched into plate during sample handling process. See Specimen Handling, the Processing of Blood Spots Using Specimen Gate for Newborn Screening, Tracking No CN003, Section VII.E.

B. Quality Controls

- 1. System Quality Controls (SQC)
 - a. Refer to Sections V.A.1.b., V.A.2.b., and V.a.3.b. System Quality Controls (SQC) are supplied ready for use in the TSH, 17-OHP, and IRT kits.
 - b. Blood spot System Quality Controls are punched into plate during sample handling process. See Specimen Handling, the Processing of Blood Spots Using Specimen Gate for Newborn Screening, Tracking No CN003, Section VII.E.
- 2. Tray Quality Controls (TQC) are enriched with TSH and 17-OHP and are supplied by the Genetic Disease Laboratory. A separate TQC is enriched with IRT and supplied by the Genetic Disease Laboratory. Run a TQC at the beginning and end of each tray for each run.

VII. Procedures

- A. Warning and Precautions for Users
 - 1. The kit contains reagents manufactured from human blood components. The source materials have been tested by immunoassay for hepatitis B surface antigen, anti-hepatitis C, and anti-HIV antibodies and found to be negative Nevertheless, all blood derivatives, including patient specimens and blood spot tray quality controls, should be considered potentially infectious and all recommended precautions for the handling of such should be observed. Refer to the U.S. Department of Health and Human Services (Bethesda, MD, USA) publication No. (CDC) 88-8395 on laboratory safety procedures.
 - 2. Reagents contain sodium azide (NaN₃) as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
 - 3. Wear disposable gloves and safety goggles while handling reagents and neonatal blood spot specimens. Thoroughly wash hands after removing gloves.
 - 4. Dispose of all waste in accordance with your local, state, and federal regulations.
- B. Preparation of Reagents

- 1. Reconstitute the 17-OHP tracer
 - a. Use the 1500 μL fixed volume pipettor to deliver exactly 1.5 mL of distilled water to each vial.
 - b. Mix gently.
 - c. Allow to stand for at least 30 minutes before use.
 - d. Once reconstituted, store refrigerated and use for 14 days.

C. Preparation for Analysis

- 1. Turn on the AutoDELFIA plate processor. Allow 2.5 hours for the instrument to reach the set temperature.
- Turn on the monitor and process controller (PC).
 NOTE: Wallac recommends that the system be powered up at all times.

D. Setting up AutoDELFIA

- 1. View the AutoDELFIA Workstation window on the screen. The AutoDELFIA workstation software is used to control the AutoDELFIA system.
- 2. Select **AutoMate** by clicking once on the smiling face. The mouth will open and your procedure will begin.
- 3. Enter your login name. Do not enter a password. Click **OK** to continue. **NOTE:** If an invalid login name is used, a message will appear. Click **OK** to correct the error and retry. If the error occurs 3 times, click **AutoMate** to start this step again. It may be necessary to reboot the AutoDELFIA so as to affect a proper login.
- 4. View the next window. This is the Welcome screen. Click **Next.**
- 5. View the next window. This is the Unload Samples screen. Click **Next.**
- 6. View the next window. This is the Load Worklists screen.
 - a) Select the worklists by clicking on the checkboxes placed to the left. Select the worklists in the same order as was done when the AD Plates program was run. (See Specimen Handling, the Processing of Blood Spots using Specimen Gate for Newborn Screening, CN003, Ver. 6.1, Section VII.E.2)

- b) The worklists will appear in a box in the top right part of the screen as they are selected. When a worklist is highlighted, the Lot Number and Calibration Standard values will be displayed.
- c) Click **Next.**

NOTE: If at any point in setting up the AutoDELFIA, you click past a screen when you realize you have made a mistake, continue to answer prompts until you are at a screen which allows you to cancel a window. Return to the **AutoMate** icon to restart. You must clear all information related to the current run or sample load from the AutoDELFIA workstation program before restarting. To clear the information, click **Options/Reset.../OK.**

- 7. View the next window. This is the Load Samples screen. Click **Next.**
- E. Loading Control Rack 73
 - 1. View the next window. This is the Accept Controls screen.
 - 2. Click **Next.**
- F. Verify the Process Schedule
 - 1. View the next window. This is the Accept Schedule screen.
 - 2. Click **Next.**
- G. Loading the Standards
 - 1. View the next window. This is the Load Standards screen.
 - 2. Click Next.
- H. Loading the Reagents
 - 1. View the next window. This is the Load Reagents screen. Click **Show Reagents.**
 - 2. Open the AutoDELFIA plate processor lid by pulling it out and down. Remove the large black reagent rack. Fill tips and vessels as needed.
 - 3. Load in the order the assays were selected. Proceed to load the reagents into the first reagent cassette. If this is the first time that a reagent lot is used, label the reagent cassette with the barcode ID provided with the unit. The barcode is encoded for analyte, reagent lot number, and assay tray lot number.

- 4. Label the reagent cassette with the barcode such that the right end extends beyond the reagent cassette. Doing this will minimize barcode reading errors and make removing the barcode easier.
- 5. Remove the caps from the buffer bottles. Place the caps upside down on the cap holder. Check that the volumes are sufficient for the number of trays with each reagent. Place the buffers in the reagent cassettes.
- 6. Remove the caps from the tracer vials and, for 17-OHP, the antibody vial, and tap on the bench to remove any bubbles. Place caps on cap holder and place in positions indicated in Load Reagents window.
- 7. Place black caps on the tracer and antibody vials.
- 8. Place the reagent cassettes into the positions indicated in the Load Reagents window.
 - **NOTE:** Bottles of buffer and tracer contain enough reagents for 4 trays. If this is not the first time the reagents are used, the number of trays previously tested must be known to be sure sufficient volume remains for the number of trays in the run. Analyst must keep track of this information by writing the date of each run and the number of trays on the bottles of buffer.
- 9. Check that the white cylindrical plug is in the left front position of the reagent rack. The AutoDELFIA uses this plug to verify that enough dilution vessels and tips are in place and that the caps are off the buffer bottles.
- 10. Put the reagent rack back into the plate processor aligning the two white lines with the transporting block. Slide the rack to make sure it is in place.
- 11. Close the plate processor lid.
- 12. Click **OK.** The next screen will display the liquid consumption requirements. The window shows the volume of rinse solution (used to rinse the wash probes), wash solution (used to wash the trays), and Enhancement Solution needed by the plate processor. The window also show that the waste container **must have less** than the amount of waste shown. Check the solution volumes to ensure that there are substantially more than the volumes shown.
- 13. Click **OK.** Click **Next**. The plate processor moves the barcode reader into position to read the barcodes on each of the reagent cassettes for reagent and tray lot numbers.
 - a. If a barcode cannot be read, "No reagent barcode found" will appear. Correct the error and click **Retry.**

- b. If a barcode is for the wrong reagent lot, "Invalid kit lot number detected" will appear. Correct the error and click **OK.**
- 14. View the window as it is updated with the reagent lot numbers. The AutoDELFIA will then lift the sample probes and move the arm out of the way to the left.

I. Loading the Trays

- 1. Wait until the Load Plates window appears and the AutoDELFIA plate processor brings the first tray holder out to the loading position.
 - **NOTE:** Make sure the frame of each tray is down snug and flush with the rest of the tray before loading; otherwise tray jam-up inside AutoDELFIA can occur.
- 2. Load the plates in the order shown on the Load Plates window. The downloaded worklist will not allow you to load the trays out of order. Place the plate into the plate holder with the barcode facing towards the plate processor and reflected in the mirror. The barcode is encoded for the analyte, lot number, and production sequence number.
- 3. Press the lit **IN/OUT** button and the tray will be taken into the plate processor. The barcode is read and checked against the corresponding reagents and tray lot numbers.
 - a. If the barcode cannot be read, "No plate barcode found" appears.
 - 1) Press **OK** to return the plate to the loading position.
 - 2) Correct the error and retry.
 - 3) Press **IN/OUT** button to reload the tray.
 - b. If the wrong barcode is presented, "The plate is of a different analyte or does not have the same lot number as the reagent cassette does" appears.
 - 1) Press **OK** to return the tray to the loading position.
 - 2) Correct the error and retry.
 - 3) Press **IN/OUT** button to reload the tray.

4. Click **Next.**

J. Starting the Run

1. The Summary window appears. Click **Start.** The AutoDELFIA performs the following initialization steps:

- a. Pressurizes the rinse and wash bottles.
- b. Pumps Enhancement Solution through the dispense tip.
- c. Rinses the washer.
- d. Moves the reagent rack to be sure it is in position.
- e. Counts the black caps for vials of tracer and antiserum, counts the dilution vessels, counts the first and last pipet tips, and checks that the caps are off the bottles of buffer.
- f. Checks the incubator and shaker.

K. Walk Away

- 1. View the AutoDELFIA **Workstation** window. The assay schedule for each assay step, of each tray, is displayed. Assay steps are shown as a **light blue bar** for sample treatment, a **yellow bar** for sampling steps, a **red bar** for action steps, and a **blue bar** for incubation steps. Click on any assay step and see the details for start time, finish time, and total time (duration).
- 2. Walk away and return to shut down at the completion time indicated on the assay schedule.

NOTE: You may cap and place in the refrigerator the standards, buffer, tracer, and antiserum once the incubation begins for the <u>last</u> tray for that particular assay.

L. Shut Down

- 1. Proceed to shut down <u>before</u> the supervisor reviews the run. The supervisor needs to PREVENT the run if the washer test (See VII.L.13.) fails. Record any unusual occurrences or observations to aid in troubleshooting if needed.
- 2. Click **Loading**, then **Unload Plates**.
- 3. The sample processor arm will move to the left to enable unloading of the trays. **CAUTION:** The trays are not aspirated when the assay is completed. Remove carefully to avoid spillage.
- 4. Remove the first tray from the tray holder and press the **IN/OUT** button on the plate processor when lit. The unloading procedure continues until all trays have been unloaded. Click **Cancel** when there are no more trays to unload.
- 5. View the **Unloading** window. Unload the reagent rack. Remove the reagent cassette, if this step was not done during the incubation of the last tray. Remove

the black cap. Cap the bottles of tracer, antiserum, and buffer. Store refrigerated. (Each bottle has enough reagent for 4 trays). Discard the used dilution vessels. Refill Wallac pipet tips and dilution vessels as needed. Remove the waste tip tray and empty. Reload the waste tip tray and reagent rack. Click **OK** to continue.

- 6. Check the bottles of Enhancement Solution. The bottle on the left should always be full since the system pumps from the right bottle to the left bottle, then into the coated wells. Each bottle holds enough for about eight trays. The bottle cap is threaded and should be screwed on straight. Remaining amounts can be combined with another bottle, then discarded after one week.
- 7. View the next window and prompt to clear the specific information about your run from the AutoDELFIA workstation program. No result files will be deleted. Click **OK.** The system will clear the information and automatically backup the runs.
- 8. Click on **Operate**, then **Consumables**. The pressure for the rinse and wash bottles for the plate processor will be released.
 - a. Proceed with the following steps for the plate processor.
 - 1) Open the wash and rinse containers for the plate processor using the open-end wrench provided by Wallac. Slide the wrench over the top of the cap. Use the handle on the bottle and the handle on the wrench for leverage by turning each in the opposite direction (the handle on the cap goes counterclockwise).
 - Fill the wash container by adding 1 bottle of Wash Concentrate (250 mL) and 6 liters of distilled water.
 NOTE: These volumes are not volumetric, but are more appropriately thought of as "bucket" chemistry.
 - 3) Fill the rinse container with distilled water.
 - 4) Close each container tightly.
 - b. Click the **Maintenance** icon on the AutoDELFIA Workstation window. Click **Plate Processor/Waste Pumping.../OK**, for the waste pump to empty the waste bottles. This is an automatic procedure when the volume of waste is at a certain level.
 - c. If the waste bottles are not connected for automatic pumping, you may dispose of the waste manually by opening the waste bottles using the smaller open-end wrench. Empty the waste bottles before the allowable

volume, as shown in the consumable window, is reached. It is good practice to empty at the end of each day.

- 9. Click **OK** and the pressure will build up to test the bottles.
- 10. Check performance of the washer.
 - a. Click **Operate/Washer Test.../OK.** Follow the prompts and the following sequence of events will occur: the system will pressurize, wait for a tray (with uncoated strips) to be loaded, fill the wells, and wash the wells. If some wells are not filled/emptied properly, clean the washer manifold according to the instructions in Appendix B, Removing the AutoDELFIA Washer Manifold. If most wells are over filled and/or an amount of liquid is left after aspiration, this indicates a problem. Call Wallac for service.
 - b. Notify supervisor to PREVENT the run if the washer test fails.

M. Inventory

An inventory system is provided so that you can easily update all of your consumables supplied by Perkin Elmer, Bio-Rad, or GDL. Each time your inventory is updated, the new information is picked up by the GDL QA system and when your supplies are low (below a set minimum amount), GDL will place the order for your laboratory and the vendor will ship the supplies. It is the laboratory's responsibility to key enter into the system the exact number of reagent kits received. The inventory system will deduct automatically the number of strips used from the number of kits received for 17-OHP, TSH, and IRT. It is also the laboratory's responsibility to key enter the amount of all other supplies and reagents including the Red Box items received, used, and removed. For these items, the deduction is **not automatic.**

- 1. Inventory Access
 - a. Login to the supervisor's PC by entering your **login name** and **password.**
 - b. Click **Management.**
 - c. Select **Inventory** option. View the Wallac inventory window on the screen. The Inventory program is divided into several applications:
 - 1) **Menubar:** This is a standard Windows menubar. The commands appropriate for the current mode are <u>Inventory</u>, <u>Routine</u>, and <u>Help</u>.
 - 2) **Toolbar:** The toolbar is quite large with a large icon and a caption for each button. The different commands available match those available from the menus in the current mode. The different modes

are Use, Remaining, Receive, Remove, Set Current Lot, View Lots, Settings, Events/Tasks, Print, and Exit.

- 3) **Listbar:** The listbar is situated on the left side of the main screen. It is divided into several *listbar groups*. These, in turn, contain icons representing *item groups*. When a listbar groups bar is clicked, it is opened to reveal its contents. When one of the item group icons is clicked, the item list displays only items from that item group. The Headingbar is also updated. The Listbar can be customized in the Listbar Editor.
- 4) **Item List:** The Item List shows all items (and their part numbers) for the currently selected item group. Selecting an item will update the Lot drop-down list, the Headingbar, the Item picture and information as well as the Graph area.
- 5) **Lot Drop-down List:** The Lot drop-down list contains all the lots for the selected item. Selecting a lot will update the Headingbar, the Item information, and the Graph area. An entry in the list contains the lot number and expiration date. If the lot is the current one, this is also indicated.
- 6) **Headingbar:** The Headingbar shows the names of the item group and item. Also, the item group's icon is displayed at the right end of the bar. The currently selected lot number is displayed directly to the left of this icon.
- 7) **Item Description:** The current item is described in two places, the item picture beneath the lot list, and the Item information are at the right of the screen. The Item information area also displays information about the selected lot. The information shown in order is:
 - a) Item title and supplier.
 - b) Names and amounts of the units in which the item is shipped and used.
 - c) Lot number and whether the item is lot dependent.
 - d) Expiration date and days left (same as previous).
 - e) Stock level for the lot.
 - f) Whether or not this is the current lot (same as previous).

- 8) **Graph Area:** The Graph Area displays different kinds of graphs with matching description texts. To change which graph is shown, select a new one from the graph drop-down list. The basic graphs available are:
 - a) Number of Items: This graph shows the number of items in storage. For lot-dependent items the selected lot is used. Item information text above graph lists lot expiration and quantity in inventory for selected lot. You can view the sum of all lots of the item by checking the box for "Plot graph based on combined sum...".
 - b) **Percentage of Capacity:** This graph shows the percentage of the site's storage capacity for the selected item in use. For lot-dependent items the selected lot is used, for others the sum of all lots is used.

2. Menu Structure

- a. Inventory
 - 1) **View Events & Tasks:** Opens the (local) Event & Task Viewer window.
 - 2) **Print Graphs/ Reports:** Opens the dialog for printing reports & graphs.
 - 3) **Exit:** Exits the Inventory program.

b. Routine

- 1) Use Items: Opens the Use Items dialog.
- 2) **Receive Items:** Opens the Receive Items dialog.
- 3) **Remaining Items:** Opens the Remaining Items Dialog.
- 4) **Remove Items:** Opens the Remove Items dialog.
- 5) **Set Current Lot:** Sets the selected lot to current.
- 6) **View Lots:** Opens the View Lots window.

c. Help

1) **About Inventory:** Opens the about box.

3. Inventory Update

- a. Select a group (All Items, Instrument or Storage) on Listbar to update inventory of reagents and supplies. Click the item to be updated from the white box on the screen, e.g., Neonatal hTSHL or TMS-System control. The screen shows lot number, item information, and graph (percent remaining numerically/graphically). All items, except TSH, 17-OHP, IRT, AFP, HCG and uE3 reagent kits, require entry of amount used, remaining, received, and removed. Enter changes in inventory into the computer program each time that your laboratory receives shipments, uses items for testing or removes items (for example, to ship to another laboratory). For TSH, 17-OHP, IRT, AFP, HCG and uE3 reagent kits, only entries for amount received, remaining and removed are needed. There is automatic countdown of amounts used. However, if a run is aborted, the number of strips used for that run must be entered manually into the inventory program as Used.
 - 1) Click Use (for every reagent, supply item, & reagent kit), check lot number and answer the prompt, "How many xxxx have you used?" to enter the amount used. Enter the amounts in the units displayed on the screen. Click **OK**.
 - 2) Click **Remaining** to see the numbers entered by the system for the amount still in storage. If the number is different from the actual physical count of your inventory, proceed with the instructions in section VII.M.5., "Reconcile the Inventory", to adjust.
 - 3) Click **Receive**, select lot number from the drop-down list and answer the prompt.

NOTE: All lot numbers are now entered by Wallac. When you receive items with lot numbers, use the **Lot** drop down menu to select the new lot number.

- Answer the **prompt**, "How many xxxx have you received?" by entering the amounts received into the box. Enter the amounts in the units displayed on the screen.
- Select either "This shipment was received from the supplier, Wallac." Or "This shipment was received from another site.".
- Enter a valid **Order ID number** from the shipment information, if this is a shipment from the vendor.
- Click **OK**.

- 4) Click Remove and answer the prompt, "How many xxxx have you removed from storage?" to correct an error in entry of number received or to enter the amount redistributed to another NAPS laboratory.
- 4. Conversion of Next (New) Lot to Current Lot
 - a. Select the Item that needs to be converted. Use the Lot drop down menu to select the new lot number.
 - b. Click **Set Current Lot** on Toolbar. You will see on the screen, "Do you want to change the current lot

From: (current lot #)
To: (new lot #)?
Yes No

- c. Click **Yes**.
- d. Click **OK**. This converts the next lot to the current lot. If you now click the **Remaining** button, the inventory of what was the "next" lot now shows in the inventory for the current lot.
- 5. Reconcile Inventory

Reconcile your inventory for discrepancies by Monday. It is important to use the correct option to reconcile the inventory so the usage rate will not be adversely affected. The usage rate feature enables GDL to calculate when to send additional inventory to the NAPS.

- a. Select the item that has a discrepancy by clicking on it so that it is highlighted.
- b. Click **Remaining** on Toolbar for item that has a listed amount in <u>excess</u> of actual physical count <u>when the item was used for testing</u>. Click **Remove** when the item was removed from your inventory for other reasons such as shipment to another laboratory or the reagent was spilled. Click **Receive** on Toolbar for item that has an amount listed which is **less** than the actual physical count.
- c. Enter the <u>discrepancy amount</u> from actual <u>physical count</u> to adjust the inventory.
- d. Click **OK**.
- 6. Settings

- a. GDL will set the Maximum or Minimum limits for inventory items from the central site. To view the limits, click the **Settings** button and select an Item from the Item list.
- b. GDL will set the Warnings for inventory items. To view, select item from the Item list.

7. Events/Tasks

- a. Click **Events** to review actions taken by and entries made by staff.
- b. Click **Tasks** to review notices of needed orders recorded. This table will also show when a GDL person has <u>acknowledged</u> the notice for a needed order and placed the order.

8. Print

To print inventory reports:

- a. Select item to be printed.
- b. Click **Print** on Toolbar menu.
- c. Select type of printout needed.
- d. Click **Print**.
- e. Click Close.

9. Exit

- a. Click **Exit** Icon on Toolbar.
- b. Click **EXIT** on Main Menu.
- c. Select **LOG-OFF**.

N. Maintenance

The AutoDELFIA keeps track of the required maintenance. The system will not allow you to complete setting up a run unless all maintenance has been performed. There is a two day grace period. If maintenance is not completed by midnight of the second day of the grace period, a warning message appears on the screen.

If you proceed to set up the run, the system will close after you load the standards with the following message on the screen.

The AutoDELFIA system has not been maintained. The system is closed, to continue you must perform the maintenance procedures. If this cannot be done please contact Perkin Elmer. Click **OK.**

Proceed with maintenance. <u>Only under extreme circumstances</u>, you may call Perkin Elmer to override the due date.

- 1. Daily
 - a. As described when performing daily set up and shut down of the AutoDELFIA.
- 2. Weekly
 - a. Turn off the computer by using the following steps.
 - 1) Click **START** button on Window Screen.
 - 2) Click **SHUTDOWN** and select **YES** to shutdown the computer.
 - 3) Click **YES** to exit AutoDELFIA workstation.
 - 4) Click **OK** to quit the program Windows before you close down the window.
 - 5) Wait until the "Closing-Multicalc AutoDELFIA-WIACALC" dialogue appears on the screen.
 - 6) Click **END TASK** to turn the computer off.
 - b. Turn on the computer.
 - 1) Push on/off button to turn the computer on.
 - 2) Type in **USERNAME** and **PASSWORD** and press **ENTER**.
 - 3) 1235 AutoDelfia Initialization dialogue appears on the screen, then click **OK**.
 - 4) Click **YES** to process initialization.
 - c. Clean waste tip tray.
 - 1) Remove tray, empty, rinse with water and dry.

3. Biweekly

- a. Disinfect the plate processor washer and disk remover.
 - 1) Click Maintenance/Instrument Cleaning.../ Disinfect Plate processor washer/Disinfect Plate processor disk remover. Click off any other options that may be selected. Click **OK**.
 - 2) Follow instructions on the screen.
 - a) Empty the waste bottle.
 - b) Place a single reagent cassette with a buffer bottle containing 50 mL of a 0.5% bleach solution, and 2 Wallac pipette tips in the left most positions of the reagent rack.
 - c) Load a full tray of uncoated strips and press the **IN/OUT** button. The disinfecting process begins, and a message appears when completed.
 - CAUTION: The waste bottle must be emptied before and after disinfecting. The Enhancement Solution may lower the pH of the waste solution and liberate chlorine from the hypochlorite.
 - d) Click **NO** when the "Maintenance recording" window appears.

NOTE: This weekly maintenance item, when performed, triggers the automatic registration onto the AutoDELFIA. When registered, the system adds 16 (due date plus 2 day grace) to the date registered and sets the next due date, e.g., every other Monday (or Tuesday, etc.) with a 2 day grace period. Do not wait until the end of the grace period, but perform on the Monday due date. If maintenance is performed at the end of the grace period, the next maintenance is due 16 days from date performed, and therefore, would lose the concept of every other Monday as biweekly maintenance. It is acceptable to perform additional maintenance as part of troubleshooting when needed. However, do not consider the extra maintenance when deciding the next due date. The next due date is the same due date as if the extra maintenance was not done.

This also maintains the schedule in the maintenance module of the Supervisor's PC.

- b. Check the Enhancement Solution outlet for precipitate
 - 1) Obtain a flashlight. Flash it on the dispenser outlet tip and check for precipitate. There is a small ring right above the end of the tip that may look like precipitate. Removing the bottle of Enhancement Solution on the right helps to see and gain access to outlet tip.
 - 2) Wipe the tip with a cotton swab moistened with Enhancement Solution if there is build-up.
- c. Empty and refill the wash and rinse bottles.
 - 1) Refer to instructions about loading consumables in section VII.L.11-12.

4. Monthly

- a. Wash the plate processor wash solution bottle
 - 1) Empty the plate processor wash solution bottle.
 - 2) Rinse well with distilled water.
- b. Disinfect the plate processor waste bottle.
 - 1) Empty waste bottle and add 1 liter of 0.5% bleach solution. Let it stand for 30 minutes with occasional swirling.
 - 2) Rinse well with distilled water.
- c. Clean the waste bottle liquid sensor and bottle cap by wiping them with a damp cloth if there is a build up of crust.
- d. Clean covers, racks and mirrors.
 - 1) Wipe the surface of the lid over the conveyor of the plate processor with 70% alcohol.
 - 2) Wash the reagent rack and the deep well/microtiter tray holders.
 - 3) Clean the mirror on each of the 12 tray holders in the plate processor. The tray holders can be brought out from the incubator by using the **UNLOAD** plates option.

- 5. Quarterly
 - a. Perform accuracy and precision determination for the 1500 μL adjustable pipet.
 - 1) Weigh 10 tubes.
 - 2) Use the fixed volume 1500 μ L pipet to dispense 1500 μ L of distilled water into the first 10 tubes.
 - 3) Rewiegh the 10 tubes.
 - 4) Calculate the volume dispensed.
 - 5) Determine the average volume and CV for each set. Results are acceptable if within the following ranges:

Volume	Average	CV
1500 μL	1470 - 1530	1.0

If results are out, repeat.

NOTE: If your laboratory is using the same 1500 μ L fixed volume pipet to reconstitute 17-OHP Std/SQC/tracer and the uE3 Std/tracer and TMS SQC, you need to perform A&P only once a quarter.

- 6. Periodic
 - a. Enhancement Solution Flush
 - 1) Flush the enhancement tubing if:
 - a) the system has not been used for 4-5 days,
 - b) the Enhancement Solution is contaminated, or mistakenly replaced with Wash Concentrate.
 - 2) Replace the Enhancement Solution with distilled water and screw the bottle in place.

- 3) Click Maintenance/Plate Processor/Enhancement Solution flush../OK.
- 4) Replace the distilled water with Enhancement Solution and flush again, repeating step 3), above.

7. Maintenance Charts

Maintenance software and charts are programmed into the Supervisor's PC. Use the software and charts to document performance of routine maintenance. To access the maintenance software when performing weekly, biweekly, and monthly maintenance:

- a. Login with name and password.
- b. Click **Management/Maintenance**. This opens the Wallace Maintenance Screen. To document routine maintenance performed:
 - 1) Select **Task/All Task**. (If **Schedule**, **Performed**, or **Overdue** is selected, you will have a partial list of task by status.) Select **Equipment** from the bars you have access to on the left of the screen (Equipment and Tasks).
 - 2) Select the equipment type for which you are performing maintenance using the equipment list on the left of the screen, e.g., AutoDELFIA. Information for the equipment type is automatically entered into the **Tasks-All Tasks** screen.
 - 3) View **Tasks**. Entered on the screen are **Equipment type**, **Equipment**, identification by system name, and **Description**, assay for which it is used.
 - 4) Select from **Equipment** the specific instrument for which you are performing maintenance. Information for the specific instrument is automatically entered into the **Tasks for Selected Equipment** screen.
 - 5) View **Tasks for Selected Equipment**. Entered on the screen are **Type**, i.e., checklist **Status**, i.e., whether it is scheduled, performed, partial, or overdue, **Equipment**, specific instrument by name, **Due**, date maintenance is to be performed, **Grace**, number of

days after the due date before maintenance becomes overdue, **Description**, whether it is weekly, biweekly, or monthly, and **Responsible**, who has the responsibility to perform the task.

NOTE: Click on any one of the name items, e.g., **Due**, to arrange the list by the due date, each time you click the list, it goes to earliest date first or latest date first, or **Description**, to arrange the list with all weekly, biweekly, monthly maintenance listed together.

- 6) Double click on the checklist for either weekly, biweekly, or monthly. This opens the **Operator Maintenance Checklist** screen.
- 7) View the **Operator Maintenance Checklist** screen. Under the **Subtasks** bar are **Description**, description of each required routine maintenance step, **Comment**, available space for comment specific to the step, **Performed by**, automatic entry with login name after the step is checked as performed, and **Date**, automatic entry with date the step is checked.
- 8) Click on the checkbox for each maintenance step performed. Use the **Move Up** and **Move Down** icon to scroll up and down the list. When all steps are checked off, the same checklist will appear for the next due date using the scheduled date, not the performed date. Additionally, if your laboratory wants to add steps to the provided maintenance list, use the **New** icon. Click **New**, enter the new description, and click **OK**. Your laboratory has no access to the **Delete** icon.
- 9) Enter any comment in the **Comment for Selected Subtask** area for the highlighted step and it will appear in the **Comment** for the list of subtasks.
- 10) Enter any general comment in the **General Comment** area regarding the maintenance.
- 11) Click **OK**. In the Tasks for Selected **Equipment**, software automatically enters **Performed by** and **Date**. When all steps are checked off, **Status** changes to "Performed". If incomplete, the status changes to "Partial" within the grace period. If no steps are checked or is incomplete, the status changes to "Overdue" after the grace period.

NOTE: As long as the status is "Overdue", the next scheduled maintenance for that periodicity will not appear on the **Tasks for Selected Equipment**. When status changes to "Performed", the

next maintenance that appears will be the one after the completion date so that there may be missing maintenance(s). **Do not** have a gap in your maintenance schedule. Checking off or not checking off the **Supervisor Review** box does not affect the appearance of the next scheduled maintenance.

- 12) After all tasks are performed by the analyst, supervisor checks the **Supervisor Review** box which changes the status to **Supervisor** with the supervisor's log on name listed under **Performed by.**
- 13) Click **Print** to print the Operator Maintenance Checklist.
- 14) Click Exit.

VIII. Calculations

A standard (STD) curve is constructed daily from the duplicate responses for each of the standards. The standard curve is a spline fit line with log concentration on the x-axis and log response on the y-axis. The AutoDELFIA system automatically converts the instrumental readout for each sample to a concentration for each analyte using the STD curve. The completed worksheet can be viewed on the screen or printed with sequence of analysis, well/rack/position number, accession number, counts, concentration, and pertinent flags.

IX. Reporting Results

A quality control program is set up to validate results before reporting. The quality control program is designed to 1) monitor the day to day performance of the AutoDELFIA and 2) monitor the day to day performance of the methods.

A. Monitor Performance of the AutoDELFIA

Three system controls are provided by Perkin Elmer to monitor the performance of the AutoDELFIA. The system controls are formulated to contain either 17OHP, TSH, or IRT at a low, medium, and high concentration. A single replicate of each of the system controls is run along with the calibrators on tray 1 and a single replicate of each as the last 3 samples of every analytical run. The judgment of whether or not the results for the system controls are acceptable is made using the limits established by Genetic Disease Laboratory in conjunction with the application of the *Westgard* rules. *Westgard* rules are applied to the pair of results for the low, medium, and high SQC. By definition, the run is out of control if "3SD 1" (one is outside 3 SD limits), "2SD 2" (two are outside 2 SD), or "R4s" (range of SD exceeds 4 SD). The system issues a warning if "2SD 1" (one is outside 2SD), or if the assay median is outside acceptable limits. These limits and Westgard rules are part of your quality control software. The analytical run is scored automatically as being in control (green light), out of control (red light), or as a warning

(yellow light). Each result that is outside the +/-2 and 3 SD limits is appropriately flagged. System control results can be used to aid in troubleshooting the entire method in the event the results are outside acceptable limits. Specifically, the results of the system controls together with that of tray controls will assist in determining the source of error, such as the degradation of standards and/or reagents, inaccurate reconstitution of reagents, instrument malfunction, operator error, sample dilution, or inaccurate sampling.

The quality control software will plot for each AutoDELFIA the results of the system control showing the mean and acceptable limits. Access the plots using the Supervisor's PC.

B. Monitor Performance of Methods

A single tray control is provided by the department to monitor the performance of the methods. The tray control is formulated to contain 17OHP/TSH or IRT at a clinically appropriate concentration. The tray control is run exactly as the neonatal blood spot specimens. A single replicate of the tray control is run as the first sample after the calibrators and the three system controls, as the last sample on tray 1, and as the first and last blood spot sample on each subsequent tray. The judgment of whether or not the results for the tray control are acceptable is made using the limits established by Genetic Disease Laboratory in conjunction with the application of the *Westgard* rules. The same *Westgard* rules in use for the SQC are in use for the TQC. These limits and *Westgard* rules are part of your quality control software. The tray is scored automatically as being in control, out of control, or as a warning. Each result that is outside the +/- 2 and 3 SD limits is appropriately flagged. If tray control results fall outside the acceptable limits, the supervisor, in consultation with Genetic Disease Laboratory, will determine the source of error, interpret its meaning, and take corrective action.

The quality control software will plot for each AutoDELFIA the results of the tray control showing the mean and acceptable limits. Access the plots using the Supervisor's PC.

X. Procedure Notes

A. Troubleshooting

- 1. Reboot the System (system freezes during assay setup)
 - a. Turn power off to the plate processor.
 - b. Turn power off to PC.
 - c. Turn power on, in order, to plate processor, and PC.

- d. Enter Login name as **SYSTEM** and press Enter. No password is needed.
- e. Click the **Settings** icon once the AutoDELFIA Workstation window appears, then click **System...**
- f. Click **Advance** in the System Settings box.
- g. The following should be selected by default, if not, click to select.
 - 1) Automatic waste pumping
 - 2) Microtubes
- h. Click Routine/OK.
- 2. Interrupted flow of data files to the supervisor's PC

Use the Dataflow Monitor to determine where a data file is stalled.

- a. Logon at Level 2 and enter password.
- b. Select **Programs/Dataflow Monitor.** This opens the NAPS Dataflow Monitor window. For NBS, the worklist files are in the Universal Eluent Worklist or the TSH Worklists windows. Raw data for the API systems are captured in the FASPAC result files.
- c. The MultiCalc input files window contains the worklist and raw data for an NBS run. The MultiCALC results files contain the calculated data. Files flow from the "worklist" window to the FasPac window to the "input" window to the "result" window to the Database window, at which point the files are in the supervisor's PC. Whenever a completed run is not available in the supervisor's PC, open **Dataflow Monitor** to determine where a file is stalled. Call Wallac for service and provide the information to Wallac.

XI. Limitations of Procedure

Neonatal blood sample collected in **EDTA** must not be applied to the filter paper for TSH testing due to the chelating effect on europium.

XII. References

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Larrson A., Hagenfeldt, L., Vondobeln, U., Curstedt, T., Gustafsson, J. and Svensson, E., Neonatal screening for congenital adrenal hyperplasis using 17-Hydroxyprogesterone assay in filter paper blood spots, Horm. Res., 1988, 30, 235 – 240.

Torok, D., Muhl, A., Votava, F., Heinze, G., Solyom, J., Crone, J., Stockler-Ipsiroglu, S., and Waldhauser, F., Stability of 17α hydroxyprogesterone in dried blood spots after autoclaving and prolonged storage, Clin. Chem., 2002, 48, 370-372.

XIII. Appendix A

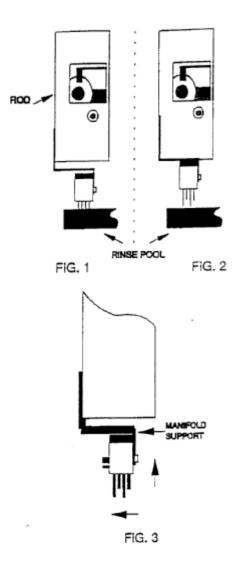
A. Cleaning the AutoDELFIA washer manifold

From time to time a need may arise for the washer manifold to be removed and cleaned e.g. foreign material lodged in a needle. If you intend to perform this procedure the following points must be noted;

We strongly advise that you wear latex gloves when carrying out any service procedure on the AutoDELFIA system.

- 1. The washer manifold <u>must</u> be put through the disinfection procedure prior to carrying out any form of maintenance.
- 2. Removal of the washer manifold must be done with care as the dispensing and aspiration needles are easily damaged. Remove the Enhancement Solution bottles first.
- 3. Follow the washer manifold removal procedure as shown at the end of this appendix.
- 4. The rubber top seal should be removed and all walls of the aspiration cavity cleaned.
- 5. The aspiration needles should be cleaned using the pin with the corresponding diameter supplied in the maintenance kit.
- 6. The dispensing needles should be cleaned with the pin with the corresponding diameter supplied in the maintenance kit.
- 7. The four silicon caps sealing the dispensing cavity (two at each end) can be removed by using a small pin. (The fifth cap on the side should not be removed). The cavity should then be thoroughly cleaned with the brush supplied in the maintenance kit. Do not use this brush for anything, else otherwise you might contaminate it and hence the manifold.

- 8. The whole unit should be flushed with distilled water.
- 9. Both dispensing and aspiration cavities should have excess water shaken out and the whole manifold either allowed to dry or wiped dry with lint free paper.
- 10. Reinstall the rubber top seal ensuring it is properly positioned.
- 11. Install new silicon caps (found in the maintenance kit) ensuring that:
 - a. the cavity access holes are dry.
 - b. all caps are inserted and positioned properly so that the top of the cap is slightly below the outer wall of the manifold.
- 12. Check that all needles are straight and correctly positioned.
- 13. Reconnect the tubing and position the manifold back in its support, checking that it can move freely up and down.
- 14. Perform a washer test to ensure all functioning and coordinates of the washer unit are correct.
- B. Removing the AutoDELFIA Washer Manifold.
 - 1. Open the lid of the instrument.
 - 2. With your left hand turn the rod (fig.1) of the washer until the manifold is completely above (fig.2) the rinse pool.
 - 3. Pull the manifold outwards until it is above the X-conveyor.
 - 4. Remove the manifold from the support by lifting it up and moving left (fig.3).
 - 5. Before disconnecting tubing from the manifold, put a paper towel on the X-conveyor so that liquid which may possibly be in the tubing, does not drop inside.



XIV. Appendix B

NBS CHECKLIST

LABORATORY SITE:	
Please FAX checklist to	GDLB Daily

	NBS LABORATORY									GDLB NBS QA							
Date	Assay Run ID#	Instrument #	Batch ID #	Accession Date		As	say		Releaser Initial & Date	Re	eviewer N	ame & Da	ate	R	deleaser Na	ame &Da	te
Run Date		Instr	Bate	Access	APSC	IRT	TSH	17ОНР	Rej	APSC	IRT	TSH	17OHP	APSC	IRT	TSH	17ОНР
Are any specimens delayed more than 2 days? Yes No]	If yes, accession	Request to Transfer Data: Date:										
									Time	: :							
Are any instruments down today?				Yes	No _]	If yes, describe	:		NAP	S Contac	t:					



Call Proxy (510) 215 - 1318

PerkinElmer LAS

855 Marina Bay Pkwy Ste 31 Richmond, CA 94804 Phone: 510-237-9405 Fax: 510-237-9492 http://das.perkinelmer.com

NAPS TELEPHONE INSTRUCTIONS

1. Follow the prompts, **Press 1** for California then enter your **Lab Number** from **Table 1**.

Lab Number	Site			
11	Western Clinical Laboratory Allied Laboratory Fresno Community Hospital			
12				
21				
31	Quest Diagnostics			
32	Memorial Med Center of Long Beach			
62	Genetic Disease Lab – Laboratory			
65	Genetic Disease Branch Genetic Disease Lab- QA Room			
69				
71	Kaiser Permanente North			
72	Kaiser Permanente South			

Table 1: Lab Number

2. Wait until prompted then **Enter** the **System ID** from Listing on page 2.

*** See Page 2 for Complete 3 Digit System ID Listings ***

- 3. At prompt **enter a call back phone #**, follow it by pressing the pound key (#).
- 4. After the Beep, **leave a voice message** give your name and a description of the problem. Press pound key (#) to end you voice message.



- 5. Wait to hear this confirmation, "A PerkinElmer Engineer will return your call".
- 6. Done

NAPS ONLY Version 14 20080327

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Not for use in QA room

ID	SYS	Description	ID	SYS	Description
151	AD1 P	AD1 PNS AutoDELFIA Plate Processor & PC	501	MM1 Q	MM1 Quattro Micro Mass Spec
152	AD2 P	AD2 PNS AutoDELFIA Plate Processor & PC	502	MM2 Q	MM2 Quattro Micro Mass Spec
153	AD3 P	AD3 NBS AutoDELFIA Plate Processor & PC	503	MM3 Q	MM3 Quattro Micro Mass Spec
154	AD4 P	AD4 NBS AutoDELFIA Plate Processor & PC	511	MM1 S	MM1 2777 AutoSampler
155	AD5 P	AD5 PNS AutoDELFIA Plate Processor & PC	512	MM2 S	MM2 2777 AutoSampler
156	AD6 P	AD6 PNS AutoDELFIA Plate Processor & PC	513	MM3 S	MM3 2777 AutoSampler
157	AD7 P	AD7 NBS AutoDELFIA Plate Processor & PC	521	MM1 P	MM1 Waters HPLC Pump
171	AD1 S	AD1 PNS AutoDELFIA Sample Processor	522	MM2 P	MM2 Waters HPLC Pump
172	AD2 S	AD2 PNS AutoDELFIA Sample Processor	523	ММ3 Р	MM3 Waters HPLC Pump
173	AD3 S	AD3 NBS AutoDELFIA Sample Processor	531	MM1 PC	MM1 Waters PC
174	AD4 S	AD4 NBS AutoDELFIA Sample Processor	532	MM2 PC	MM2 Waters PC
175	AD5 S	AD5 PNS AutoDELFIA Sample Processor	533	MM3 PC	MM3 Waters PC
176	AD6 S	AD6 PNS AutoDELFIA Sample Processor	561	PK1	MM1 PEAK N2 Generator & Argon Gas
177	AD7 S	AD7 NBS AutoDELFIA Sample Processor	562	PK2	MM2 PEAK N2 Generator & Argon Gas
201	CH1	Chrontrol Timer or Deep Well Plate Shakers	563	PK3	MM3 PEAK N2 Generator - Argon Gas
202	CH2	Chrontrol Timer or Deep Well Plate Shakers	611	HB40	HEATBLOCK 40 Degree VWR
211	TOM1	Tomtec 96 Well Pipettor	612	HB60	HEATBLOCK 60 Degree VWR
212	TOM2	Tomtec 96 Well Pipettor	621	PP1	Apricot Personal Pipettor
221	NG1	DBS Puncher for TSH, MSMS	622	PP2	Apricot Personal Pipettor
222	NG2	DBS Puncher for Universal Eluent - Hb	631	PP1 PC	Apricot PC
223	NG3	DBS Puncher for TSH, MSMS	632	PP2 PC	Apricot PC
224	NG4	DBS Puncher for Universal Eluent - Hb	641	SVR	Server PC
225	NG5	DBS Puncher for TSH, MSMS	651	TX1	3 Plate Thermomix INC/SHAKE
226	NG6	DBS Puncher for Universal Eluent - Hb	652	TX2	3 Plate Thermomix INC/SHAKE
241	BC1	PNS Barcode Printer	653	TX3	3 Plate Thermomix INC/SHAKE
242	BC2	NBS Barcode Printer	661	INC1	9 Plate Incubator Shaker
243	BC3	PNS Barcode Printer	662	INC2	9 Plate Incubator Shaker
244	BC4	NBS Barcode Printer	663	INC3	9 Plate Incubator Shaker
251	WAP1	PerkinElmer Wallac AutoPuncher	671	HS1	Heat Sealer MSMS
252	WAP2	PerkinElmer Wallac AutoPuncher	691	BR1	Branson Model 2510 Sonicator
301	SG1	Specimen Gate, Server, Router, File Transfer	692	BR2	Branson Model 2510 Sonicator
302	SG2	Specimen Gate, Server, Router, File Transfer	701	UT1	UT1 Transferase/Biotinidase System
303	SG3	Specimen Gate, Server, Router, File Transfer	702	UT2	UT2 Transferase/Biotinidase System
304	SG4	Specimen Gate, Server, Router, File Transfer	703	UT3	UT3 Transferase/Biotinidase System
311	RPC1	Specimen Gate Review Station PC	704	UT4	UT4 Transferase/Biotinidase System
312	RPC2	Specimen Gate Review Station PC	901	SS1	SIS- Data Terminal, Server or Scanner-F
313	RPC3	Specimen Gate Review Station PC	902	SS2	SIS- Data Terminal, Server or Scanner-F
314	RPC4	Specimen Gate Review Station PC	903	SS3	SIS- Data Terminal, Server or Scanner-F
			904	SS4	SIS- Data Terminal, Server or Scanner-F
			905	SS5	SIS- Data Terminal, Server or Scanner-F
			906	SS6	SIS- Data Terminal, Server or Scanner-F
			907	SS7	SIS- Data Terminal, Server or Scanner-F
			908	SS8	SIS- Data Terminal,Server or Scanner-F
104			952	SC2	SIS - Optical Scanner
			951	SC1	SIS - Optical Scanner